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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,725	09/16/2003	Siau-Way Liew	3155/119	4659

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EXAMINER	
RAMIREZ, JOHN FERNANDO	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
11/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,725	LIEW ET AL.	
	Examiner	Art Unit	
	JOHN F. RAMIREZ	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-172* is/are pending in the application.

4a) Of the above claim(s) *1-11,14-88,106-115 and 131-172* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,89-105 113 and 116-130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant alleges that the Jiang et al. patent does not teach or suggest converting a region of interest to a 2D trabecular pattern and then deriving quantitative data from the pattern. However, the examiner of record respectfully disagrees with applicant's comments. In figures 5A-5B, and in col. 12 lines 54-67; col. 13 line1-53; col. 17 lines 15-31, the specifications of the Jiang et al. patent teach converting a region of interest to a 2D trabecular pattern and then deriving quantitative data from the pattern. Therefore, the rejection is maintained and repeated below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13, 89-99, 101-105 and 116-130 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The phrase "converting the region of interest to a 2D trabecular pattern" is considered to be new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 12, 89-91, 93-98-103, 118-119 and 124-130 are rejected under 35 U.S.C. 102(e) as being anticipated by Jiang (US 6,442,287).

Jiang discloses an automated method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including population data such as age of the

patient, were used to determine the strength of bone and thus the likelihood of risk of future fracture. One of the variables is the 3D orientation of the trabecular network. Since 3D trabecular orientation is invasive or destructive, Jiang uses texture orientation to estimate the 3d structural information of the 3d orientation of the trabecular network from a non invasive and non destructive projection radiograph (two-dimensional image). This extracted structural features is then further used to generate texture information such as the Minkowski dimension (fractal dimension) and the volumetric bone mass density (abstract, col. 6 line 27-65, col. 17 line 15-47, col. 20 line 22-42, see figs. 1A and 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 103, 118, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herren et al. (US 6,108,635) in view of Jiang et al. (US 6,442,287).

Herren discloses an integrated disease information system that inputs disease information, and then analyses the data and provide an output. The system also provides integrated management and analysis of multiple data sources of population data of the disease information (col. 1 line 20-28). Herren discloses a specific example

of the use of his system is to determine volumetric structure of the bone and related issues of osteoporosis. The system can input a simulation model of bone remodeling and the user inputs parameters such as of a therapeutic intervention and the user can see what kind of changes each particular therapeutic intervention causes to determine the best therapy to prescribe. Although Herren does not explicitly disclose that a simulation of bone remodeling to be the disease progression, the system is capable of doing so, and it would be helpful to have a control case to compare each of the therapeutic interventions to (col. 27-65). Although Herren does not disclose how the information that is inputted into the system is obtained, it would be obvious to one skilled in the art at the time of the invention to use any known method to obtain disease information for inputting into the system of Herren such as the method disclosed in Jiang above. Herren also discloses that this system can be automated (col. 46 line 45-54).

Claims 116-117, 120-122 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumagai (US 6,306,822 B 1) in view of Jiang et al. (US 6,442,287).

Kumagai discloses a method for treating or preventing any condition associated with bone loss through administering an agent to the subject. The bone quality measurement is first measured on day 0, before treatment begins, then again on day 45 and day 90. The bone quality is then compared, showing the effectiveness of each of the agents on remodeling the bone (fig. 5, col. 13 line 60-63). Kumagai does not disclose the specifics on how they measure the bone density. It would be obvious to

one skilled in the art at the time of the invention to use any method that is well known in the art such as the method that is disclosed in Jiang, which is explained above in section 102(e).

Claims 13, 92, and 104-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (US 6,442,287).

In regards to **claims 13, 104-105 and 113,** Jiang et al. disclose an automated method for analyzing bone wherein the strength of the bone is estimated and analyzed (see abstract). Jiang et al. do not disclose the total bone factor as claimed in claim 13, and converting the 2D pattern into a 4D pattern as claimed in claims 104, 105 and 113.

It would have been an obvious design choice for one of ordinary skill in the art at the time for the invention to have expected Jiang et al. method and applicant's invention, to perform equally well. Furthermore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the method disclosed by Jiang et al., to obtain the invention as specified in claims 13, 104-105 and 113 because such a modification would have considered a mere design consideration which fails to patentably distinguish over the prior art of Jiang et al.

In regards to **claim 92**, it would have been prima facie obvious to one of ordinary skill in the art to have modified the method disclosed by Jiang et al., by using the image of a horse to analyze bone mass and structure for the assessment of bone strength and/or osteoporosis since it is well known that osteoporosis can occur in both human and animal subjects.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

/J. F. R./
Examiner, Art Unit 3737